

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

FILED

SAN ANTONIO DIVISION

FEB 25 2016

UNITED STATES OF AMERICA

v.

VASCULAR SOLUTIONS, INC.,

and

HOWARD C. ROOT

Defendants.

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CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY A. Nowlin
DEPUTY

CRIMINAL NO. 5:14-CR-00926

FINAL JURY INSTRUCTIONS

Members of the Jury:

In any jury trial there are, in effect, two judges. I am one of the judges; the other is the jury. It is my duty to preside over the trial and to decide what evidence is proper for your consideration. It is also my duty at the end of the trial to explain to you the rules of law that you must follow and apply in arriving at your verdict.

First, I will give you some general instructions which apply in every case, for example, instructions about burden of proof and how to judge the believability of witnesses. Then I will give you some specific rules of law about this particular case, and finally I will explain to you the procedures you should follow in your deliberations.

You, as jurors, are the judges of the facts. But in determining what actually happened—that is, in reaching your decision as to the facts—it is your sworn duty to follow all of the rules of law as I explain them to you.

You have no right to disregard or give special attention to any one instruction, or to

question the wisdom or correctness of any rule I may state to you. You must not substitute or follow your own notion or opinion as to what the law is or ought to be. It is your duty to apply the law as I explain it to you, regardless of the consequences.

It is also your duty to base your verdict solely upon the evidence, without prejudice or sympathy. That was the promise you made and the oath you took before being accepted by the parties as jurors, and they have the right to expect nothing less.

The indictment or formal charge against a defendant is not evidence of guilt. Indeed, the defendant is presumed by the law to be innocent. The defendant begins with a clean slate. The law does not require a defendant to prove his innocence or produce any evidence at all and no inference whatever may be drawn from the election of a defendant not to testify.

The government has the burden of proving the defendant guilty beyond a reasonable doubt, and if it fails to do so, you must acquit the defendant. While the government's burden of proof is a strict or heavy burden, it is not necessary that the defendant's guilt be proved beyond all possible doubt. It is only required that the government's proof exclude any "reasonable doubt" concerning the defendant's guilt.

A "reasonable doubt" is a doubt based upon reason and common sense after careful and impartial consideration of all the evidence in the case. Proof beyond a reasonable doubt, therefore, is proof of such a convincing character that you would be willing to rely and act upon it without hesitation in making the most important decisions of your own affairs.

As I told you earlier, it is your duty to determine the facts. To do so, you must consider only the evidence presented during the trial. Evidence is the sworn testimony of the witnesses, including stipulations, and the exhibits. The questions, statements, objections, and arguments made by the lawyers are not evidence.

The function of the lawyers is to point out those things that are most significant or most helpful to their side of the case, and in so doing to call your attention to certain facts or inferences that might otherwise escape your notice. In the final analysis, however, it is your own recollection and interpretation of the evidence that controls in the case. What the lawyers say is not binding upon you.

During the trial I sustained objections to certain questions and exhibits. You must disregard those questions and exhibits entirely. Do not speculate as to what the witness would have said if permitted to answer the question or as to the contents of an exhibit. Also, if certain testimony or evidence has been ordered removed from the record and you have been instructed to disregard this evidence do not consider that testimony or other evidence which has been removed from your consideration in reaching your decision. Your verdict must be based solely on the legally admissible evidence and testimony.

Also, do not assume from anything I may have done or said during the trial that I have any opinion concerning any of the issues in this case. Except for the instructions to you on the law, you should disregard anything I may have said during the trial in arriving at your own verdict.

In considering the evidence, you are permitted to draw such reasonable inferences from the testimony and exhibits as you feel are justified in the light of common experience. In other words, you may make deductions and reach conclusions that reason and common sense lead you to draw from the facts which have been established by the evidence.

Do not be concerned about whether evidence is "direct evidence" or "circumstantial evidence." You should consider and weigh all of the evidence that was presented to you.

The law makes no distinction between the weight to be given either direct or circumstantial evidence. But the law requires that you, after weighing all of the evidence, whether direct or circumstantial, be convinced of the guilt of the defendant beyond a reasonable doubt before you can find the defendant guilty.

I remind you that it is your job to decide whether the government has proved the guilt of the defendant beyond a reasonable doubt. In doing so, you must consider all of the evidence. This does not mean, however, that you must accept all of the evidence as true or accurate.

You are the sole judges of the credibility or "believability" of each witness and the weight to be given to the witness's testimony. An important part of your job will be making judgments about the testimony of the witnesses who testified in this case. You should decide whether you believe all, some part, or none of what each person had to say, and how important that testimony was. In making that decision I suggest that you ask yourself a few questions: Did the witness impress you as honest? Did the witness have any particular reason not to tell the truth? Did the witness have a personal interest in the outcome of the case? Did the witness have any relationship with either the government or the defense? Did the witness seem to have a good memory? Did the witness clearly see or hear the things about which he testified? Did the witness have the opportunity and ability to understand the questions clearly and answer them directly? Did the witness's testimony differ from the testimony of other witnesses? These are a few of the considerations that will help you determine the accuracy of what each witness said.

Your job is to think about the testimony of each witness you have heard and decide how much you believe of what each witness had to say. In making up your mind and reaching a verdict, do not make any decisions simply because there were more witnesses on one side than on the other. Do not reach a conclusion on a particular point just because there were more

witnesses testifying for one side on that point. You will always bear in mind that the law never imposes upon a defendant in a criminal case the burden or duty of calling any witnesses or producing any evidence.

The testimony of an alleged accomplice, and/or the testimony of one who provides evidence against a defendant for immunity from punishment or for personal advantage or vindication, must always be examined and weighed by the jury with greater care and caution than the testimony of ordinary witnesses. You, the jury, must decide whether the witness's testimony has been affected by these circumstances, by the witness's interest in the outcome of the case, by prejudice against the defendant, or by the benefits that the witness has received either financially or as a result of being immunized from prosecution.

You should keep in mind that such testimony is always to be received with caution and weighed with great care. You should never convict any defendant upon the unsupported testimony of such a witness unless you believe that testimony beyond a reasonable doubt.

You will note that the indictment charges that the offense was committed on or about a specified date. The government does not have to prove that the crime was committed on that exact date, so long as the government proves beyond a reasonable doubt that the defendant committed the crime on a date reasonably near the date stated in the indictment.

You are here to decide whether the government has proved beyond a reasonable doubt that the defendant is guilty of the crime charged. The defendant is not on trial for any act, conduct, or offense not alleged in the indictment. Neither are you called upon to return a verdict as to the guilt of any other person or persons not on trial as a defendant in this case, except as you are otherwise instructed.

If a defendant is found guilty, it will be my duty to decide what the punishment will be. You should not be concerned with punishment in any way. It should not enter your consideration or discussion.

Title 18, United States Code, Section 371, makes it a crime for anyone to conspire with someone else to commit an offense against the laws of the United States or to defraud the United States or any agency thereof in any manner of for any purpose.

The defendants are charged with conspiring to introduce misbranded medical devices into interstate commerce and conspiring to defraud the United States by concealing their distribution of medical devices for unapproved use on perforator veins in order to impair and defeat the lawful function of the FDA and other law enforcement agencies.

The word "defraud" here is not limited to its ordinary meaning of cheating the government out of money or property; it also includes impairing, obstructing, defeating, or interfering with the lawful function of the government or one of its agencies by dishonest means.

A "conspiracy" is an agreement between two or more persons to join together to accomplish some unlawful purpose. It is a kind of "partnership in crime" in which each member becomes the agent of every other member.

For you to find each defendant guilty of this crime, you must be convinced that the government has proved each of the following beyond a reasonable doubt:

First: That the defendant and at least one other person made an agreement to commit at least one of the following crimes: (1) introducing misbranded devices into interstate commerce, as charged in the indictment, or (2) defrauding the United States, as charged in

the indictment. The government does not have to prove both of these for you to return a guilty verdict on this charge. Proof beyond a reasonable doubt on one is enough. But in order to return a guilty verdict, all of you must agree that the same one has been proved. That is, all of you must agree that the government proved beyond a reasonable doubt that the defendant conspired to commit the criminal offense of introducing a misbranded medical device into interstate commerce during the time frame charged in the superseding indictment, or all of you must agree that the government proved beyond a reasonable doubt that the defendants conspired to conceal from a federal government agency the criminal offense of introducing a misbranded medical device into interstate commerce;

Second: That the defendant knew the unlawful purpose of the agreement and joined in it willfully, that is, with the intent to further the unlawful purpose; and

Third: That one of the conspirators during the existence of the conspiracy knowingly committed at least one of the overt acts described in the indictment, in order to accomplish some object or purpose of the conspiracy.

One may become a member of a conspiracy without knowing all the details of the unlawful scheme or the identities of all the other alleged conspirators. If a defendant understands the unlawful nature of a plan or scheme and knowingly and intentionally joins in that plan or scheme on one occasion, that is sufficient to convict him for conspiracy even though the defendant had not participated before and even though the defendant played only a minor part.

The government need not prove that the alleged conspirators entered into any formal agreement, nor that they directly stated between themselves all the details of the scheme. Similarly, the government need not prove that all of the details of the scheme alleged in

the indictment were actually agreed upon or carried out. Nor must it prove that all of the persons alleged to have been members of the conspiracy were such, or that the alleged conspirators actually succeeded in accomplishing their unlawful objectives.

Mere presence at the scene of an event, even with knowledge that a crime is being committed, or the mere fact that certain persons may have associated with each other, and may have assembled together and discussed common aims and interests, does not necessarily establish proof of the existence of a conspiracy. Also, a person who has no knowledge of a conspiracy, but who happens to act in a way which advances some purpose of a conspiracy, does not thereby become a conspirator.

A conspirator is responsible for offenses committed by other conspirators if the conspirator was a member of the conspiracy when the offense was committed and if the offense was committed in furtherance of, or as a foreseeable consequence of, the conspiracy.

Therefore, if you have first found the defendant guilty of the conspiracy charged in Count One and if you find beyond a reasonable doubt that during the time the defendant was a member of that conspiracy, other conspirators committed the offenses in Counts Two through Five in furtherance of and as a foreseeable consequence of that conspiracy, then you may find the defendant guilty of Counts Two through Five, even though the defendant may not have participated in any of the acts which constitute the offenses described in Counts Two through Five.

The events presented at trial happened in various places. There is no requirement that the entire conspiracy take place in the Western District of Texas, but in order for you to return a guilty verdict, the government must prove by a preponderance of the evidence that either the agreement or an overt act took place in this district, even if the defendant never set foot in the

district. An overt act is an act performed to effect the object of a conspiracy, although it remains separate and distinct from the conspiracy itself. Though the overt act need not be of criminal nature, it must be done in furtherance of the object of the conspiracy.

Unlike the other elements of the offense, this is a fact that the government has to prove only by a preponderance of the evidence. This means the government has to convince you only that it is more likely than not that part of the conspiracy took place in the Western District of Texas. All other elements of the offense must be proved beyond a reasonable doubt. You are instructed that Austin and San Antonio are located in the Western District of Texas.

Counts Two through Five of the indictment charge the defendants with the introduction of a misbranded device into interstate commerce, a crime that is often referred to as “misbranding.” In order to find the defendants guilty of misbranding, you must find the following elements beyond a reasonable doubt:

One: That the Vari-Lase products listed in Counts Two through Five were “devices”;

Two: That those products were “misbranded”;

Three: That the defendants caused those products to be introduced into interstate commerce.

I will define each of these elements in the instructions that follow.

“Interstate commerce” means commerce between any state and any place outside of that state, including another state. The Vari-Lase products were introduced into interstate commerce if VSI distributed them across state lines.

A “device” is “an instrument, . . . machine, . . . or related article, including any component, part, or accessory, which is . . . intended for use . . . in . . . treat[ing] or prevent[ing] of disease” or is “intended to affect . . . [the] function[ing] of the [human] body”

The Indictment alleges that the Vari-Lase products were misbranded for two reasons. First, the Indictment alleges that Vari-Lase products were misbranded because VSI did not provide the FDA with a premarket notification (referred to as a “510(k) notification”) as required by law before distributing the Vari-Lase in interstate commerce. Second, the Indictment alleges that the Vari-Lase products were misbranded because their labeling did not have adequate directions for use. You must find beyond a reasonable doubt that the Vari-Lase products were misbranded for at least one of these two reasons in order to find either defendant guilty of misbranding.

The government does not have to prove both of these theories for you to return a guilty verdict on this charge. Proof beyond a reasonable doubt on one is enough. But in order to return a guilty verdict, all of you must agree that the same theory has been proved. That is, all of you must agree that the government proved beyond a reasonable doubt that Vascular Solutions was required by the law to provide the FDA with a premarket notification before introducing the Vari-Lase console or kit charged in the superseding indictment, but failed to do so; or, all of you must agree that the government proved beyond a reasonable doubt that the Vari-Lase console or kit charged in the superseding indictment did not have adequate information for a licensed doctor to use the device safely for its intended use.

According to the allegations in the Indictment, the first reason why the Vari-Lase products were misbranded is that VSI failed to provide the FDA with a 510(k) notification as required by law. A device is misbranded if the manufacturer was required to, but failed to provide, a 510(k) notification or information related to that notification as required by law before distributing the device. When a device is already in commercial distribution but is about to be significantly changed in its design or intended use, the manufacturer must submit a new 510(k) notification to the FDA at least 90 days before the manufacturer introduces the modified device into interstate commerce. Significant changes that require a premarket notification include: (1) a change in the device that could significantly affect the safety or effectiveness of the device (e.g., a significant change or modification in design or manufacturing process); or (2) a major change in the intended use of the device.

The 510(k) notification must include appropriate supporting evidence to show that the manufacturer has considered what consequences and effects the changes might have on the safety and effectiveness of the device. A 510(k) notification also must contain proposed labeling sufficient to describe the device, its intended use, and the directions for its use.

If a 510(k) notification does not contain sufficient information, the FDA may request additional information. If the additional information is not provided within 30 days of the request, the 510(k) notification is considered withdrawn.

According to the allegations in the Indictment, the second reason why the Vari-Lase products were misbranded is because their labeling failed to provide adequate information for use. The government must prove beyond a reasonable doubt that the labeling for the Vari-Lase products did not contain adequate information for use, including methods of administration and

any relevant hazards and precautions, under which a doctor can use the device safely and for the purpose for which it is intended.

The Indictment alleges that perforator vein ablation was an intended use of the Vari-Lase products. The term “intended use” refers to the objective intent of VSI when it sold the devices. In determining intended use, you may consider, for example, the devices’ labeling, oral or written statements by VSI or its representatives, the circumstances surrounding the distribution of the devices, or any other relevant source. Further, a doctor’s independent decision to use the Vari-Lase products to ablate perforator veins is not evidence of VSI’s intended use for those products.

Doctors may use medical devices that have been approved or cleared for one use for a different use that has not been cleared or approved by the FDA. This is often referred to as unapproved use or off-label use. This is not illegal. It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI’s promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.

The United States is not required to prove that Defendants knew about or intended to commit the misbranding violations in Counts Two through Five. If Defendants caused the introduction into interstate commerce of misbranded devices, then they are guilty of misbranding.

In order to find that Defendant Howard Root caused a misbranding violation, you must find beyond a reasonable doubt that, by reason of his position in the corporation, he had the

responsibility and authority either to prevent or promptly correct the violation, and that he failed to do so.

One of the defendants, VSI, is a corporation. As a corporation, VSI can only act through its officers and employees. VSI is not automatically guilty of anything that its employees do. VSI is criminally responsible for the unlawful actions of its agents, who are acting with an intent to benefit the corporation, provided that the conduct is within the scope of the agent's authority, whether actual or apparent. A corporation may be criminally responsible even if there is no actual benefit to the corporation.

Actual authority means that the corporation's management authorized the action. Apparent authority is authority that outsiders would normally assume the agent to have, judging from his position with the company and the circumstances surrounding his past conduct. If the agent's action benefits the corporation, this is a relevant fact that can support a finding of apparent authority.

A corporation can be criminally responsible even for the actions of a low-level employee, if the employee acted with actual or apparent authority. A corporation can be responsible for the criminal actions of an employee even if there is a general corporate policy prohibiting the conduct, if the employee acted with actual or apparent authority.

VSI and Howard Root maintain that perforator veins were covered by the FDA-cleared indications. The 2007 510(k) notification was submitted in accordance with FDA Guidance in order to add perforators and two other specific veins to the Vari-Lase label. But defendants maintain that the law did not require a new 510(k) submission. They accordingly maintain that they are not guilty of all charges.

To reach a verdict, whether it is guilty or not guilty, all of you must agree. Your verdict must be unanimous on each count of the indictment. Your deliberations will be secret. You will never have to explain your verdict to anyone.

It is your duty to consult with one another and to deliberate in an effort to reach agreement if you can do so. Each of you must decide the case for yourself, but only after an impartial consideration of the evidence with your fellow jurors. During your deliberations, do not hesitate to reexamine your own opinions and change your mind if convinced that you were wrong. But do not give up your honest beliefs as to the weight or effect of the evidence solely because the opinion of your fellow jurors, or for the mere purpose of returning a verdict.

Remember at all times, you are judges—judges of the facts. Your duty is to decide whether the government has proved the defendant guilty beyond a reasonable doubt.

When you go to the jury room, the first thing that you should do is select one of your number as your foreperson, who will help to guide your deliberations and will speak for you here in the courtroom.

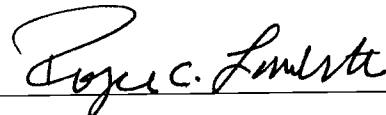
A verdict form has been prepared for your convenience.

The foreperson will write the unanimous answer of the jury in the space provided for each count of the indictment, either guilty or not guilty. At the conclusion of your deliberations, the foreperson should date and sign the verdict.

If you need to communicate with me during your deliberations, the foreperson should write the message and give it to the court security officer. I will either reply in writing or bring you back into the court to answer your message.

Bear in mind that you are never to reveal to any person, not even to the court, how the jury stands, numerically or otherwise, on any count of the indictment, until after you have

reached a unanimous verdict.

A handwritten signature in cursive script, reading "Royce C. Lamberth".

Royce C. Lamberth
United States District Judge

Date: 2/25/14